EXHIBIT 2

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION *This document relates to:* *City of Cleveland, et al. v. Purdue Pharma L.P., et al.*, Case No. 18-OP-45132; *County of Cuyahoga, et al. v. Purdue Pharma L.P., et al*., Case No. 17-OP-45004; *County of Summit, et al. v. Purdue Pharma, L.P. et al*., Case No. 18-OP-45090	MDL 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster Mag. Judge David A. Ruiz

PLAINTIFFS THE CITY OF CLEVELAND, COUNTY OF CUYAHOGA, COUNTY OF SUMMIT AND CITY OF AKRON'S SUPPLEMENTAL AMENDED RESPONSES AND OBJECTIONS TO THE MANUFACTURER DEFENDANTS' FIRST SET OF INTERROGATORIES, SUBMITTED PURSUANT TO DISCOVERY RULING NO. 13

Set out below, on behalf of Plaintiffs Cuyahoga and Summit Counties and the Cities of Akron and Cleveland ("Plaintiffs") is the supplemental response to the Manufacturer Defendants' Interrogatory No. 6, which was the subject of Discovery Ruling 5, as amended by the Court on October 16, 2018, and Discovery Ruling No. 13.

While maintaining their objections to the interrogatories and to Discovery Ruling No. 5, as set forth in Plaintiffs' prior letters, briefing, and oral argument, Plaintiffs respond below. In particular, and without waiving any other objections,

This response is provided only with respect to the Bellwether jurisdictions listed above, and is not binding on any other plaintiff in the MDL.

Manufacturer Interrogatory No. 6

Identify and describe 500 prescriptions of opioids that were written in [Plaintiff's jurisdiction] in reliance on any alleged misrepresentations, omissions, or other alleged wrongdoing by any Defendant. Include in the response the healthcare provider; the patient; the date of prescription; which opioid or opioids were prescribed; the specific misrepresentation, omission, or wrongdoing that allegedly caused the prescription to be written; the Defendant and the specific sales representative(s), employee(s), or agent(s) of the Defendant that made or committed the

alleged misrepresentation, omission, or wrongdoing; the person or persons to whom the alleged misrepresentation or omission was made or to whom the alleged wrongdoing was directed; and whether, by whom, and for how much the prescription was approved for reimbursement. Your response must include at least 10 prescriptions for an opioid sold by each manufacturing defendant.

Plaintiffs' Supplemental Amended Response:

Bellwether Plaintiffs will not assert, either in expert opinions or factual presentations at trial, that any specific prescription was caused by Defendants' deceptive marketing. Plaintiffs intend to rely, at trial and in expert opinions, on a theory of aggregate proof in asserting that Defendants' conduct violated the law and caused their damages and/or created a public nuisance, as alleged more fully in their Complaints and proved at trial. Notwithstanding this response, and solely for the purpose of preserving Plaintiffs' right to present additional evidence in expert opinions and at trial to address the harm alleged to Plaintiffs, as opposed to individuals, and to address any contingencies that come to light during discovery, Bellwether Plaintiffs revise and supplement their prior response to Manufacturer Interrogatory No. 6 as follows. This response supersedes the prior response submitted by Plaintiffs.

Plaintiffs reassert all objections and reservations in their prior responses and submissions in response to Discovery Ruling No. 5 as if asserted here. Plaintiffs also note and preserve their objections to being required to answer all of the interrogatories subject to Discovery Ruling 5, *see* Plaintiffs' Memorandum in Opposition to Manufacturer Defendants' Motion to Compel Compliance with Discovery Ruling No. 5, Doc. 1071 (Nov. 1, 2018).[1] *See* Order Regarding Discovery Ruling #5, Doc. 1047 (Oct. 16, 2018). Plaintiffs were authorized, under the Court's October 16, 2018 Order, to choose among the alternatives offered, and expressly preserve their position that the Court's Order Regarding Discovery Ruling #5 (Doc. 1047) is clear in this respect. Each Interrogatory is a separate request, and Plaintiffs may choose to answer those related to the harm caused by Defendants' conduct, preserving their ability to present individualized proof of these substantial harms, while relying solely on aggregate proof in proving the impact of Defendants' marketing on the prescribing and use of opioids. *See* Order Regarding Discovery Ruling #5, Doc. 1047 (Oct. 16, 2018) (amending Discovery Ruling No. 5 "as follows: Instead of answering the disputed interrogatories as required by the Discovery Ruling, Plaintiffs may instead elect not to answer them ***on the condition*** that Plaintiffs instead categorically and affirmatively respond to the disputed interrogatories by stating that: (1) they will not assert, either in expert opinions or factual presentations at trial, that any specific prescriptions "were unauthorized, medically unnecessary, ineffective, or harmful" or that "the filling of [any specific prescriptions] that caused or led to harm for which [Plaintiffs] seek to recover," and (2) Plaintiffs instead will rely, at trial and in expert opinions, solely on a theory of aggregate proof.") (footnote omitted); Letter from M. Dearman, on behalf of Bellwether Plaintiffs, to Special Master David R. Cohen, Re: *In re National Prescription Opiate Litigation, MDL No. 2804*, Plaintiffs' Response In Opposition to Manufacturer Defendants' Motion to Compel Immediate and Full Compliance With Discovery Ruling 5, dated November 14, 2018 (Nov. 26, 2018). This is especially true because the other interrogatories that are the subject of Discovery Ruling 5 seek information about prescriptions that were harmful or unnecessary, while Interrogatory 6 seeks information about the extent to which doctors relied on Defendants' wrongful conduct. Given that these are distinct

[1] Unless otherwise noted, all references to "Doc. __" refer to the master docket in this MDL.

subjects, relating to different elements of Plaintiffs' claims, there is no reason why Plaintiffs should be required to make the same election with respect to proof of the one subject as they make with respect to proof of the others.

Bellwether Plaintiffs further renew their objections to responding to this reformulated interrogatory for the reasons laid out in their briefing and oral argument related to Discovery Ruling 5 and in their Memorandum in Opposition to Manufacturer Defendants' Motion to Compel Compliance with Discovery Ruling No. 5. *See* Letter from M. Dearman, on behalf of Bellwether Plaintiffs, to Special Master David R. Cohen, Re: *In re National Prescription Opiate Litigation, MDL No. 2804*, Plaintiffs' Response In Opposition to Manufacturer Defendants' Motion to Compel Immediate and Full Compliance With Discovery Ruling 5, dated November 14, 2018 (Nov. 26, 2018) and oral arguments on behalf of Bellwether Plaintiffs. Without narrowing or limiting those objections here, Bellwether Plaintiffs note that Defendants have failed to answer the same discovery request (Interrogatory No. 17 to the Manufacturer Defendants, and No. 21 for the Purdue Pharma Defendants), yet demand Bellwether Plaintiffs do so without an adequate record and/or the benefit of expert witness testimony. In addition, responding to this Interrogatory requires Bellwether Plaintiffs to obtain and analyze information outside of Plaintiffs' custody and control. Pursuant to Federal Rule of Civil Procedure 33(d), this question can be answered, to the extent practicable, from business records already produced to Defendants or within Defendants' custody and control. Nonetheless, the Plaintiffs are complying with the Court order in good faith and with the limitations laid out below.

The discovery request is a contention interrogatory. "Contention" interrogatories seek to clarify the basis for or scope of an adversary's legal claims. *Starcher v. Corr. Med. Sys., Inc.*, 144 F.3d 418, fn. 2 (6th Cir. 1998), *aff'd sub nom. Cunningham v. Hamilton Cty., Ohio*, 527 U.S. 198, 119 S. Ct. 1915, 144 L. Ed. 2d 184 (1999). To be clear, it is the position of the Plaintiffs answering herein, that the answer to this contention interrogatory does not, consistent with Discovery Ruling 7, limit Plaintiffs' experts from using different criteria to identify prescriptions written in reliance on Defendants' misrepresentations, omissions, or other wrongdoing, or from contending that there are existing additional prescriptions that would be responsive, in addition to those identified herein. Discovery Ruling No. 7, p. 6.

Responding to this Interrogatory does not waive Bellwether Plaintiffs' rights to prove their claims, in whole or in part, through aggregate proof or statistical evidence. Bellwether Plaintiffs reserve their rights to assert that the use of any individualized prescription information is inappropriate, irrelevant, or inadmissible. *See* Report and Recommendation, *In re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804 (DAP), Doc. 1025 (N.D. Ohio) (Magistrate Judge David A. Ruiz); *In re Neurontin Litigation*, 712 F.3d 21, 29-39 (1st Cir. 2013); *United States v. Life Care Centers of Am., Inc.*, 114 F. Supp. 3d 549 (E.D. Tenn. 2014); *United States v. Life Care Centers of Am., Inc.*, 1:08-CV-251, 2015 WL 10987029, at *3 (E.D. Tenn. Feb. 18, 2015); Order Regarding Discovery Ruling No. 5, *In re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804 (DAP), Doc. 1047 (N.D. Ohio). In short, by responding, Bellwether Plaintiffs do not concede that this information is relevant or admissible.

Further, Bellwether Plaintiffs also object to this Interrogatory as overly broad and unduly burdensome as propounded. Plaintiffs object on the grounds that this Interrogatory seeks

information not relevant to any party's claim or defense or the legal theories in this case. Bellwether Plaintiffs note that they are not representing or seeking recovery on behalf of any individuals who were harmed by opioids or any payer of opioid prescription costs (other than Bellwether Plaintiffs); nor have Plaintiffs alleged any claims for restitution for their own spending or other individual claims that justify the burden of interrogatories this broad in scope. Plaintiffs further object to the Interrogatory because they are not proportional to the needs of the case considering (1) the lack of relevance or importance of the materials to the claims and defenses in this litigation, as described above, and (2) the substantial burden they place on the Bellwether Plaintiffs to identify and describe all individual prescriptions that would cause substantial harm to the privacy interests and rights held by the individuals whose private medical files are the subject of this request. Plaintiffs further object to the extent these interrogatories call for Confidential Information not in the Plaintiff's possession and protected by privacy laws, including but not limited to, the federal Health Insurance Portability and Accountability Act ("HIPAA") Title 42, Part 2 of the Code of Federal Regulations.

In responding, Bellwether Plaintiffs disclaim any reliance on or reference to their own claims data. Instead, Bellwether Plaintiffs rely upon other information produced by the parties in discovery, and information obtained from public records and a Rule 45 subpoena.

Bellwether Plaintiffs produce this highly sensitive identified health information subject to the Special Master's prior order limiting the disclosure of this information to Defendants' attorneys and their experts only and preventing the use of such information for further discovery without separate order of the Court. *See* Track One Discovery Order Regarding Health-Related Information, *In re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804 (DAP), Doc. 703 (N.D. Ohio) (Special Master Cohen). Plaintiffs' production of data in response to this Interrogatory is subject to prior rulings limiting the disclosure and use of claims and health related information.

Despite repeated requests that Defendants provide prescription and sales tracking data, Defendants have failed to produce all or, in some instances, *any* of that information. In addition, to Plaintiffs' knowledge, Defendants have not provided all or, in some instances, *any* documents responsive to Request for Production No. 13 to the Manufacturer Defendants (No. 14 for the Purdue Pharma Defendants), which seeks documents and data "regarding prescribing, sales, distribution, use, consumer or medical community perceptions, insurance coverage of, or diversion, misuse or abuse (including overdoses, hospitalizations, or other injuries or fatalities) of Opioids . . ." When the Pharmacy Defendants refused to produce dispensing data, Bellwether Plaintiffs raised the issue with Special Master Cohen, who issued Discovery Ruling 8, requiring these Defendants to produce data related to the prescriptions they dispensed in the bellwether jurisdictions. *See* Discovery Ruling No. 8, *In re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804 (DAP), Doc. 1055, (N.D. Ohio) (Special Master Cohen). Plaintiffs have not yet received that data from the majority of Defendants. Thus, because of Defendants' own failure to provide prescription-level data, Bellwether Plaintiffs are responding to this Interrogatory without the benefit of full discovery.

Bellwether Plaintiffs reserve the right to supplement these answers when or if Defendants fully and proportionately respond to discovery and once expert reports and opinions are disclosed.

For the purposes of responding to this contention Interrogatory, and consistent with the Court's Order, Bellwether Plaintiffs have not attempted to identify every prescription that was caused or influenced by Defendants' unlawful, improper, and deceptive marketing, Plaintiffs, nor all deceptive statements or omissions made to prescribers in the jurisdictions. Thus, identifying prescriptions as written in reliance on Defendants' misrepresentations, omissions, or other alleged wrongdoing does not mean that these prescriptions were not also medically unnecessary or unauthorized. Likewise, in contending that Defendants misrepresented the risk of addiction to opioids (and identifying prescriptions to patients who developed opioid use disorder), Bellwether Plaintiffs do not contend that Defendants only misrepresented the risk of addiction; they may also have misrepresented the benefits or superiority of opioids, or understated other risks.

Subject to and without waiving the foregoing objections and limitations, Bellwether Plaintiffs contend that all prescriptions of opioids for chronic pain in the Bellwether Jurisdictions were written in reliance on the misrepresentations, omissions, and wrongdoing alleged in their complaints. Plaintiffs contend that, based on misrepresentations and omissions of material fact regarding their products and opioids more generally, prescribers initiated and/or maintained patients on opioids, often at increasingly and dangerously high doses, switched them to extended-release or purportedly abuse-deterrent formulations, added immediate-release and/or rapid-onset opioids for "breakthrough" pain, and failed to monitor for or recognize signs of addiction or abuse. Defendants' deceptive marketing also increased the comfort level of doctors and patients in converting opioids prescribed for acute pain— surgery or injuries, for example— to long-term use by patients who experienced or reported ongoing pain.

As explained in the Bellwether Plaintiffs' complaints, historically, opioids were used only to treat short-term acute pain or for palliative (end-of-life) care because they were considered too addictive and debilitating for the treatment of chronic pain, like back pain, migraines, and arthritis. Purdue, joined by the other "Manufacturing" or "Marketing" Defendants, set out to change this practice, and to maintain this shift with false and deceptive messages. As a doctor who became a "key opinion leader" or "KOL" for Manufacturing Defendants, Dr. Russell Portenoy wrote in 1994 — before the launch of OxyContin and marketing campaign that attended it — the prevailing attitudes regarding the dangers of long-term use of opioids were as follows:

> *The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs.* This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects,*

> *avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*[2]

See Corrected Second Amended Complaint and Jury Demand, *The County of Summit, Ohio, et al. v. Purdue Pharma, L.P. et al.*, No. 18-op-45090 ("Summit/Akron SAC") ¶ 406.[3] According to Dr. Portenoy, the foregoing problems could constitute "compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."[4] *Id.*

Given the history of opioid abuse in the U.S. and the medical profession's resulting wariness, the commercial success of the Marketing Defendants' prescription opioids would not have been possible without a fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use. Defendants devoted massive resources to accomplishing and, as concerns began to surface, to maintaining, this fundamental shift in perception. Each Defendant spent, and some continue to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids and overstate the benefits of opioids. Meanwhile, they also promoted themselves as compassionate, concerned corporate citizens who sought to solve a public health problem of undertreated pain while keeping their drugs out of the hands of "bad apple" patients or others who might seek to divert them into illicit uses or channels.

For example, and without waiving any additional conduct described in Bellwether Plaintiffs' Complaints or developed through investigation and/or discovery, Plaintiffs contend Defendants disseminated these misrepresentations and omissions through:

- Sales representatives who visited prescribers in the Bellwether jurisdictions and through medical liaisons who responded to questions from these prescribers,[5] and at programs and conferences that prescribers in the Bellwether jurisdictions attended. Visits and attendance at these programs are reflected in Defendants' call notes, ride-along-reports, and other documents, along with the sales representations' descriptions of these visits. In addition, Defendants' marketing plans, scripts, talking points, FAQs, and similar documents Defendants provided to their sales representatives and medical liaisons also reflect the messages that Defendants directed their employees and key opinion leaders to provide.

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[2] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields & J.C. Liebeskind eds., 1994) (emphasis added).

[3] For the sake of brevity, the Bellwether Plaintiffs have provided citations to the Summit/Akron SAC only. The same allegations also appear in the respective Corrected Second Amended Complaint and Jury Demands filed in *County of Cuyahoga, et al. v. Purdue Pharma L.P., et al*., Case No. 17-op-45004 and *City of Cleveland, et al. v. Purdue Pharma L.P., et al.*, Case No. 18-op-45132. The contentions cited herein are made by each of the Bellwether Plaintiffs.

[4] *Id.*

[5] This includes prescribers outside of the Bellwether jurisdictions whose prescribing caused the Bellwether Plaintiffs damages or contributed to the public nuisance in the jurisdictions.

- Publications and websites funded, published, edited, approved, and/or disseminated by Defendants that were provided to or visited by prescribers and patients in the Bellwether jurisdictions. These include, for example, Purdue's "Partners Against Pain," Janssen's "Let's Talk Pain," books such as Mallinckrodt's C.A.R.E.S. Alliance's "Defeat Chronic Pain Now!," Responsible Opioid Prescribing, and brand-specific leave behinds for Defendants' drugs. These publications were handed out to prescribers by sales representatives, given out at programs, and featured in catalogs or lists of references promoted or distributed by Defendants.

Continuing Medical Education ("CME") and "speakers" programs. A CME is a professional education program provided to doctors, dentists, pharmacies, pharmacists, nurses, and other allied medical providers. These programs are delivered in person, often in connection with professional organizations' conferences, and online, or through written publications, and /or contractual agreements with other Defendants. Doctors, dentists, pharmacies, pharmacists, nurses, and other allied medical providers rely on CMEs not only to satisfy licensing requirements, but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors. The Marketing Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in the Bellwether Plaintiff's complaints. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects. Among Defendants' specific misrepresentations and omissions distributed to prescribers in the Bellwether jurisdictions, and reserving the right to present additional misrepresentations and omissions identified through discovery and expert reports and opinions, were claims that:

a. The risk of addiction from chronic opioid therapy is low

b. To the extent there is a risk of addiction, it can be easily identified and managed

c. Signs of addictive behavior are "pseudoaddiction," requiring more opioids

d. Opioid withdrawal can be avoided by tapering

e. Opioid doses can be increased without limit or greater risks

f. Long-term opioid use improves functioning

g. Alternative forms of pain relief pose greater risks than opioids

h. OxyContin provides twelve hours of pain relief

i. New formulations of certain opioids successfully deter abuse

Summit/Akron SAC ¶ 179. These nine categories of misrepresentations are offered to organize the numerous statements the Marketing Defendants made and to explain their role in the overall marketing effort, not as a checklist for assessing each Marketing Defendant's liability. The following chart identifies examples from the Bellwether Plaintiffs' complaints, without waiving the right to rely on or prove any additional conduct described in the complaint or developed through investigation and/or discovery:

Falsehood	**Explanation**
The risk of addiction from chronic opioid therapy is low	When it launched OxyContin, Purdue cited in promotional and educational materials a single paragraph from a letter published in 1980 by Dr. Hershel Jick and Jane Porter in the New England Journal of Medicine as evidence of the low risk of addiction to opioids. In fact, Purdue included reference to this letter in a 1998 promotional video entitled, "I got my life back," in which Dr. Alan Spanos states, "In fact, the rate of addiction amongst pain patients who are treated by doctors is much less than 1%." Until April 2012, Endo stated on its website that "…patients treated with prolonged opioid medicines usually do not become addicted;" a statement echoed on the website of its close affiliate, APF. Endo also published and distributed multiple pamphlets and brochures downplaying addiction as it related to opioids. For example, "Living with Someone with Chronic Pain", stated, "Most health care providers who treat people with pain agree that most people do not develop an addiction problem.[6] Other publications, include but not limited to "Pain: Opioid Facts," "Understanding Your Pain: Taking Oral Opioid Analgesics" and "Pain: Opioid Therapy." Janssen claimed on its unbranded website – www.PrescribeResponsibility.com – that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients." Janssen also published a patient education guide entitled "Finding Relief: Pain Management for Older Adults" describing opioid addiction as a myth and that "many studies show opioids are *rarely* addictive…" which, until recently, was available online. Cephalon sponsored a 2007 publication from APF entitled "Treatment Options: A Guide for People Living with Pain" which taught that opioid addiction is rare. Actavis published material that claimed it is "less likely" to become addicted to opioids in those who "have never had an

[6] ENDO-CHI_LIT-00195455.

Falsehood	Explanation
	addiction problem." The same publication notes that a need for a "dose adjustment" is the result of tolerance, and "not addiction." A 2007 guide for prescribers published under Actavis's copyright states that Kadian is more difficult to abuse and less addictive than other opioids.[7] Mallinckrodt created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance in 2010 which promoted a book entitled "Defeat Chronic Pain Now!" in which opioids were stated to "rarely" cause addiction.
To the extent there is a risk of addiction, it can be easily identified and managed	Purdue and Cephalon sponsored the APF's publication, "Treatment Options: A Guide for People Living with Pain" in 2007, which falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed." Janssen stated on its website – www.PrescribeResponsibly.com – that opioid addiction "can usually be managed" through tools such as opioid agreements between patients and doctors. Purdue also sponsored a 2011 webinar taught by Dr. Lynn Webster entitled "Managing Patient's Opioid Use: Balancing the Need and Risk" wherein prescribers were told that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths." Endo paid for a 2007 supplement for continuing education credit in the "Journal of Family Practice" entitled "Pain Management Dilemmas in Primary Care: Use of Opioids" which recommended screening patients and the use of the Opioid Risk Tool.
Signs of addictive behavior are "psuedoaddiction," requiring more opioids	Cephalon, Endo and Purdue sponsored the Federation of State Medical Board's ("FSMB") publication entitled "Responsible Opioid Prescribing" in 2007 which stated that such behaviors as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids and hoarding are all signs of "pseudoaddiction" (not genuine addiction). Purdue published an unbranded pamphlet entitled "Clinical Issues in Opioid Prescribing" in 2005 which was circulated through 2007 and available on its website through 2013. This pamphlet stated that "illicit drug use and deception" were not evidence of true addiction, but rather "pseudoaddiction." Endo sponsored a CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which promoted pseudoaddiction. Janssen sponsored, funded and edited a website entitled "Let's Talk

[7] ACTAVIS0006823.

Falsehood	Explanation
	Pain" which in 2009 stated that pseudoaddiction "…refers to patient behaviors that may occur when pain is undertreated…"
Opioid withdrawal can be avoided by tapering	Endo sponsored an educational program entitled "Persistent Pain in the Older Adult" which claimed that withdrawal symptoms could be avoided by simply tapering a patient's opioid dose over ten days. Similarly, Purdue sponsored APF's publication "A Policymaker's Guide to Understanding Pain & Its Management" which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation." Neither Defendant explained the significant hardships associated with cessation of use.
Opioid doses can be increased without limit or greater risks	Purdue omitted the increased risk of respiratory distress and death from increasing opioid dosage from its 2010 "Risk Evaluation and Mitigation Strategy" for OxyContin. Endo published on its website a patient education pamphlet entitled "Understanding Your Pain: Taking Oral Opioid Analgesics" that responds to the question, "If I take the opioid now, will it work later when I really need it?" with "The dose can be increased…You won't 'run out' of pain relief." Purdue and Cephalon also sponsored APF's 2007 "Treatment Options: A Guide for People Living with Pain" which taught patients that opioids have "no ceiling dose" and are therefore safer than NSAIDs.
Long-term opioid use improves functioning	Janssen promoted Duragesic through an ad campaign as improving a patient's functioning and work productivity. Janssen's "Let's Talk Pain" website featured a video interview claiming that opioids were what allowed a patient to "continue to function." Similarly, Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association stating, "There Can Be Life With Relief" and implying that OxyContin would help users' function; however the FDA noted that Purdue failed to warn that patients could die from taking OxyContin. Purdue also ran advertisements in medical journals in 2012 touting that OxyContin would help a "writer with osteoarthritis of the hands" work more effectively. Since May 2011, Endo has distributed and made available on its website – www.Opana.com – a pamphlet implying that patients with physically demanding jobs would achieve long-term pain relief and functional improvement. Mallinckrodt's website claims that "[t]he effective pain management offered by our [opioids] helps enable patients to stay in the workplace, enjoy

Falsehood	Explanation
	interactions with family and friends, and remain an active member of society."
Alternative forms of pain relief pose greater risks than opioids	Purdue and Cephalon sponsored APF's publication entitled "Treatment Options: A Guide for People Living with Pain" warning of increased risks if NSAIDs are "taken for more than a period of months;" falsely attributing 10,000 to 20,000 deaths annually to NSAID overdoses when the figure is closer to 3,200. In 2009, Janssen sponsored a publication entitled, "Finding Relief: Pain Management for Older Adults" which listed dose limitations as "disadvantages" of other pain medicines. It also listed a number of serious health effects as disadvantages of NSAIDs while only listing "upset stomach or sleepiness" and constipation as disadvantages of opioids. Purdue and Endo sponsored a CME issued by the AMA in 2003, 2007, 2010 and 2013 entitled "Overview of Management Options" which taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.
OxyContin provides twelve hours of pain relief	In 2000, Purdue advertised that OxyContin provides "Consistent Plasma Levels Over 12 Hours;" however the oxycodone does not enter the body at a linear rate, releasing a greater proportion upon administration and gradually tapering over 12 hours. These 12-hour dosing advertisements ran in the *Journal of Pain* in February 2005 and the *Clinical Journal of Pain* in 2006.
New formulations of certain opioids successfully deter abuse	Purdue presented an article in 2013 based on a review of data from poison control centers concluding that its ADF OxyContin can reduce abuse, but failed to acknowledge that abuse merely shifted to other drugs and that there were actually more harmful exposures to opioids after the reformulation. In 2016, Dr. J. David Haddox, VP of Health Policy for Purdue, falsely claimed that the evidence does not show Purdue's ADF opioids are being abused in large numbers. Endo's promotion of its Opana ER also tended to omit material facts according to a May 2012 letter from the FDA to Endo. Endo submitted a citizen petition asking the FDA for permission to label Opana ER as abuse-resistant, and also went so far as to sue the FDA to force expedited consideration of this change. Endo falsely promoted Opana ER as having been designed to be crush-resistant, knowing that this would (falsely) imply that it was actually crush-resistant and less likely to be abused (as stated in a June 14. 2012 press release). Endo initiated journal advertisements that appears in April 2013 stating Opana ER was "designed to be crush resistant."

Falsehood	Explanation
	Likewise, Actavis copyrighted a guide for prescribers representing that Kadian is more difficult to abuse and less addictive than other opioids.[8] Mallinckrodt promoted both Exalgo and Xartemis XR as specifically formulated to reduce abuse, going so far as to state, "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."
Endo: "[M]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted." *Taking a Long-Acting Opioid: What Does It Mean to Me* (2008); Caregiver Booklet (2009).	This is demonstrably false and misleading.

Further, public statements by the Defendants and their agents or proxies created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact. Purdue serves as a hallmark example of such wrongful conduct. At the heart of Purdue's public outreach is the claim that it works closely with law enforcement and government agencies to combat opioid abuse and diversion. Mallinckrodt similarly claims to be "committed . . . to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances, ..." Additional public statements were made on Defendants' behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations. *See, e.g.*, Summit/Akron SAC ¶¶ 594-606.

In fact, however, Defendants failed to report suspicious orders and prescribers, prevent diversion, or otherwise control the supply of opioids following into communities across America. Despite the notice described above, and in disregard of their duties, Defendants continued to pump massive quantities of opioids despite their obligations to control the supply, prevent diversion, report and take steps to halt suspicious orders and report suspicious prescribers. *See, e.g.*, Summit/Akron SAC ¶¶579-593.

[8] ACTAVIS0690598.

In addition, as noted above, Bellwether Plaintiffs contend that these prescriptions were written in reliance on the false, fraudulent, and misleading effort by Defendants to distort the standard of care to favor prescribing opioids for chronic pain. As alleged in Plaintiffs' Complaints, Defendants funded, suggested, edited, cited, and distributed articles and publications written by key opinion leaders, including Russell Portenoy, Scott Fishman, and Lynn Webster, which deceptively represented the risks, benefits, and superiority of opioids for chronic pain. Similarly, both directly and through these key opinion leaders, Defendants funded, influenced, edited, cited, and distributed treatment guidelines, patient education materials, studies, and other publications in ways that overstated the benefits of long-term opioid use and trivialized its risks. These included, for example, the 1997 American Academy of Pain Medicine ("AAPM") "consensus statement," which also formed the foundation of the Federation of State Medical Boards ("FSMB") Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines"), the 2009 Guidelines issued by AAPM and the American Pain Society ("APS"), and the guidelines for "Pharmacological Management of Persistent Pain in Older Persons" disseminated by the American Geriatrics Society ("AGS") in 2002 and 2009, and books such as *A Clinical Guide to Opioid Analgesia* and *Responsible Opioid Prescribing*. Defendants also used existing guidelines, like Pain as a Fifth Vital Sign and the World Health Organization's cancer pain ladder to suggest that opioids, including extended relief and rapid onset opioids, were an appropriate first line treatment for chronic pain and that doctors, even outside of the hospital setting, should routinely ask about and treat pain with their opioids. The CDC has recognized that treatment guidelines can "change prescribing practices."[9]

As described in their Complaints, Bellwether Plaintiffs contend that Defendants hid their involvement in these efforts, depriving prescribers of the ability to critically evaluate the recommendations, and frequently misrepresented the strength or nature of the recommendations, for instance, citing the AAPM/APS Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines or their financial backing of the authors of these Guidelines," or citing a letter to the editor in the *New England Journal of Medicine* as sole support for their assertion that patients rarely become addiction to opioids if it were a credible, peer-reviewed study.[10] As one of Defendants' KOLs, Dr. Portenoy later admitted: "I gave so many lectures to primary care audiences in which the [letter to the editor in the New England Journal of Medicine] was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*."[11]

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[9] Deborah Dowell, M.D., *et al*., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States 2016*, 65(1) Morbidity & Mortality Wkly. Rep. 1, 21 (Mar. 18, 2016) (hereinafter, "CDC Guideline"), at 2.

[10] Jane Porter & Herschel Jick, M.D., *Addiction Rare in Patients Treated with Narcotics*, 302(2) New Engl. J. Med. 123 (Jan. 10, 1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

[11] Harrison Jacobs, *This 1-Paragraph Letter May Have Launched the Opioid Epidemic,* AOL (May 26, 2016, 1:39 PM), https://www.aol.com/article/2016/05/26/letter-may-have-launched-opioid-epidemic/21384408/. Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011).

Plaintiffs further contend that Defendants' scheme was not a haphazard effort, but a carefully orchestrated campaign designed to produce a return on their massive investment. Defendants planned their messages in advance and expected their efforts to pay off in increased prescriptions. For example, a marketing memo sent to Purdue's top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase. *See* Summit/Akron SAC ¶ 155. Internal documents also reflect that they monitored the success of their efforts. Internal emails from Endo staff, for example, attributed increases in Opana ER sales to the aggressiveness and persistence of sales representatives. As another example, according to an internal Janssen training document, sales representatives were told that sales calls and call intensity have high correlation to sales. *See* Summit/Akron SAC ¶ 490. Defendants also had detailed prescription data from both third-party data vendors and financial arrangements with distributors that allowed them to target their marketing to maximize its impact.

Plaintiffs also note that the effects of sales calls on prescribers' behavior is well documented in the literature, including a 2017 study that found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers. *See* Summit/Akron SAC ¶ 493. Studies also show that drug marketing techniques are so refined and advanced that many prescribers persuaded by the companies will not necessarily even recognize that they have been influenced. Thus, denial by a physician that his or her prescribing conduct was influenced by Defendants' statements and/or omissions in no way establishes that there was no influence or reliance.

Individually and, especially, collectively, these misrepresentations and omissions caused prescribers and patients in the Bellwether jurisdictions to prescribe and take, respectively, opioids in instances, at higher doses, and for durations that they would not have been considered prior to Defendants' deceptive marketing. Plaintiffs refer Defendants to the list of prescriptions previously produced in connection with their October 24 2018 and November 1, 2018 submissions in response to Discovery Ruling No. 5 and with their Amended Responses to the Manufacturer Defendants' First Set of Interrogatories and the National Retail Pharmacy Defendants' First Set of Interrogatories, served November 2, 2018, as sufficient to identify and describe 500 prescriptions of opioids that were written in each Plaintiff's jurisdiction in reliance on any alleged misrepresentations, omissions, or other alleged wrongdoing by any Defendant, including at least 10 prescriptions for an opioid sold by each manufacturing defendant. *See* Discovery Ruling No. 13 Regarding Various Matters at 7 (Doc. 1215) ("Plaintiffs have sufficiently identified the connections between the prescriptions and misstatements at issue.").

As explained in Plaintiffs' Amended Responses to the Manufacturer Defendants' First Set of Interrogatories and the National Retail Pharmacy Defendants' First Set of Interrogatories, served November 2, 2018, Bellwether Plaintiffs contend that each prescription in the previously-provided Exhibit A was the result of Manufacturer Defendants' deceptive marketing. Based upon a review of relevant call notes, Bellwether Plaintiffs contend that Manufacturer Defendants systematically omitted or misrepresented the risk of addiction, failed to accurately disclose the risk of addiction, provided false assurance that addiction is rare among patients taking opioids for pain and/or

can be identified or managed, and failed to disclose that the risk of addiction increased with longer duration of opioid use or at higher doses, including, upon information and belief, to each of these prescribers. In addition to sales representatives' visits to prescribers, Manufacturer Defendants communicated this misinformation through written publications, websites, and programs that were available to or disseminated in the jurisdictions.[12]

Exhibit A includes individuals who were prescribed reformulated OxyContin, Hysingla ER, Opana ER, Exalgo, and Xartemis XR as abuse-deterrent formulations of Defendants' opioids. Bellwether Plaintiffs contend that the Manufacturers of these products systematically misrepresented to prescribers that these products were actually abuse-deterrent, when they were not approved as abuse-deterrent and did not actually deter abuse, misrepresented that these products could not be tampered with or reduced abuse, and/or failed to disclose that abuse-deterrent formulations had no impact on oral abuse, the primary means of abusing opioids.

The prescriptions for Actiq, Fentora, and Subsys included in Exhibit A were prescribed to individuals who did not have a recent diagnosis of cancer. Bellwether Plaintiffs contend that Defendants Teva and Insys pervasively and unlawfully marketed Actiq, Fentora, and Subsys for off-label use for chronic pain, and to doctors who did not regularly treat cancer pain, even though the drugs were approved only for breakthrough cancer pain for opioid-experienced patients. Teva and Insys failed to disclose that Actiq, Fentora, and Subsys were not approved or appropriate for chronic pain, or were not to be used by opioid-naïve patients.[13]

Dated: December 31, 2018

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[12] In identifying specific deceptive statements, in addition to the description set forth above, Bellwether Plaintiffs also incorporate by reference their 3rd Amended Responses to Manuf. 1st Set of Interrogatories (10/8/2018) and the Response to Distr. 4th Set of Interrogatories (8/31/2018): which describe specific statements made to identified prescribers in the jurisdictions, including prescribers identified in Exhibit A.

[13] Where Bellwether Plaintiffs have not provided information, such as prescription information for individuals listed in Exhibit B, Plaintiffs do not presently have or have access to this information. To the extent that such information becomes available to Bellwether Plaintiffs, Plaintiffs will supplement this response.

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CERTIFICATE OF SERVICE

I, David I. Ackerman, certify that on December 31, 2018, I caused the foregoing to be served via electronic mail on Defendant's Liaison Counsel pursuant to the Case Management Order in this case (Dkt. No. 232).

/s/ David I. Ackerman